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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

J & J Reference: DEP 671

MMB Docket No. 1671-0213

Group Art Unit: 3732

Application of: Gundlapalli et al.

Examiner: P. Philogene

Serial No.: 10/061,513

Filed: February 1, 2002

Title: **Method and Apparatus for Surgically Preparing a Tibia for Implantation of a Prosthetic Implant Component which has an Offset Stem**

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Paul J. Maginot

Name of person mailing Document or Fee

*Paul J. Maginot*  
Signature

April 25, 2005

Date of Signature

LETTER

Sir:

Enclosed is an Appeal Brief in connection with the above-identified patent application. The Notice of Appeal was filed on February 24, 2005, and the Appeal Brief was due two months from this date (i.e. 04/24/05). Since the due date of filing the Appeal Brief fell on Sunday, April 24, 2005, the Appeal Brief is being timely filed on Monday, April 25, 2005. Also enclosed herewith is a check for \$500.00 to cover the fee required under 37 CFR 1.17(c).

Additionally, please provide any extension of time which may be necessary and charge any fees which may be due to Account No. 13-0014, but not to include any payment of issue fees.

Respectfully submitted,

April 25, 2005  
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Signature of person mailing Document or Fee

April 25, 2005

Date of Signature

**APPEAL BRIEF**

Mail Stop Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is an appeal under 37 CFR § 1.191 to the Board of Patent Appeals  
and Interferences of the United States Patent and Trademark Office from the

final rejection of the claims 1-18 and 21-28 of the above-identified patent application. These claims were indicated as finally rejected in an Office Action dated November 24, 2004. Enclosed herewith is the \$500.00 fee required under 37 CFR § 1.17(c). Also, please provide any extensions of time that may be necessary and charge any fees that may be due to Deposit Account No. 13-0014, but not to include any payment of issue fees.

**(1) REAL PARTY IN INTEREST**

DePuy Orthopaedics, Inc. is the assignee of this patent application, and the real party in interest.

**(2) RELATED APPEALS AND INTERFERENCES**

There are no appeals or interferences related to this patent application (serial no. 10/061,513).

**(3) STATUS OF CLAIMS**

Claims 1-28 are pending in the application.

Claims 1-28 are finally rejected.

Claims 1-18 and 21-28 are being appealed.

Claims 19-20 are not being appealed.

Each of claims 1-18 and 21-28 is shown in the Claim Appendix attached to this Appeal Brief.

#### **(4) STATUS OF AMENDMENTS**

Appellants have filed no amendments subsequent to the final rejection contained in the Office Action mailed November 24, 2004.

#### **(5) SUMMARY OF CLAIMED SUBJECT MATTER**

A first aspect of Appellants' invention relates to a method of surgically preparing a tibia 20 for implantation of a prosthetic implant 100. (See, e.g., Appellants' specification at page 9, lines 5-8; and Figs. 13, 14, 23, and 25.) The method includes securing a tray trial 12 to a proximal end 18 of the tibia 20, wherein the tray trial 12 defines a plate opening 36 therethrough, the plate opening 36 having a center point 50. (See, e.g., Appellants' specification at page 9, lines 5-10; page 10, lines 1-2 and 9-10; page 18, line 18 through page 19, line 2; and Figs. 1, 13, 14, and 17.) The method further includes advancing a first bone working tool 124 through the plate opening 36 to form a first hole 128 in the tibia 20. (See, e.g., Appellants' specification at page 19, lines 7-9; and Fig. 18.) In addition, the method includes securing a tool guide 16, 16' to the tray trial 12, wherein the tool guide 16, 16' defines a first bore 64, 64' and a second bore 66, 66', each of the first 64, 64' and second 66, 66' bores having a center point 72, 72' offset from the center point 50 of the plate opening 36. (See, e.g., Appellants' specification at page 9, lines 3-5; page 12, lines 3-22; page 20, lines 3-13; page 24, lines 4-20; page 25, lines 4-9; and Figs. 7-9, 19-21, and 24-25.) The method also includes determining a direction of offset of a medullary canal of the tibia 20 from a center of the tibia 20. (See, e.g., Appellants' specification at page 19, line

19 through page 20, line 5; page 25, lines 2-19; and Figs. 19-21, 23, and 25.) Moreover, the method includes advancing a second bone working tool 124 through one of the first bore 64, 64' and the second bore 66, 66' that corresponds to the direction of offset of the medullary canal to form a second bore 130 in the tibia 20. (See, e.g., Appellants' specification at page 21, lines 1-14; page 25, lines 6-16; and Figs. 20 and 25.) Furthermore, the method includes detaching the tool guide 16, 16' from the tray trial 12 without any bone drill having been previously advanced through the other of the first bore 64, 64' and the second bore 66, 66' while the tool guide 16, 16' was secured to the tray trial 12. (See, e.g., Appellants' specification at page 23, lines 1-7; and Figs. 19-23 and 25.) Additionally, the method includes detaching the tray trial 12 from the proximal end 18 of the tibia 20 without any bone drill having been previously advanced through the other of the first bore 64, 64' and the second bore 66, 66' while the tray trial 12 was secured to the proximal end 18 of the tibia 20. (See, e.g., Appellants' specification at page 23, lines 1-7; and Figs. 19-23 and 25.)

A further aspect of the invention relates to a method of surgically preparing a tibia 20 for implantation of a prosthetic implant 100. (See, e.g., Appellants' specification at page 9, lines 5-8; and Figs. 13, 14, 23, and 25.) The method includes the step of securing a tray trial 12 to a proximal end 18 of the tibia 20, wherein the tray trial 12 defines a plate opening 36 therethrough, the plate opening 36 having a center point 50. (See, e.g., Appellants' specification at page 9, lines 5-10; page 10, lines 1-2 and 9-10; page 18, line 18 through page 19, line 2; and Figs. 1, 13, 14, and 17.) The method further includes advancing a

first bone working tool 124 through the plate opening 36 at the center point 50 to form a first hole 128 in the tibia 20. (See, e.g., Appellants' specification at page 19, lines 7-9; and Fig. 18.) In addition, the method includes securing a first guide 16, 16' to the tray trial 12, wherein the first guide 16, 16' defines a first bore 64, 64' and a second bore 66, 66', each of the first 64, 64' and second 66, 66' bores having a center point 72, 72' offset from the center point 50 of the plate opening 36. (See, e.g., Appellants' specification at page 9, lines 3-5; page 12, lines 3-22; page 20, lines 3-13; page 24, lines 4-20; page 25, lines 4-9; and Figs. 7-9, 19-21, and 24-25.) The method also includes advancing a second bone working tool 124 through one of the first bore 64, 64' and the second bore 66, 66' to form a second bore 130 in the tibia 20. (See, e.g., Appellants' specification at page 21, lines 1-14; page 25, lines 6-16; and Figs. 20 and 25.)

Another aspect of the present invention relates to a surgical assembly 10 for preparing a tibia 20 for implantation of a prosthetic implant 100. (See, e.g., Appellants' specification at page 9, lines 5-8; and Figs. 13, 14, 23, and 25.) The surgical assembly 10 includes a tray trial 12 adapted to be secured to a proximal end 18 of the tibia 20 and defining a plate opening 36 therethrough, the plate opening 36 having a center point 50. (See, e.g., Appellants' specification at page 9, lines 5-10; page 10, lines 1-2 and 9-10; page 18, line 18 through page 19, line 2; and Figs. 1, 13, 14, and 17.) The surgical assembly 10 further includes a first guide 16, 16' adapted to be secured to the tray trial 12, wherein the first guide defines at least a first bore 64, 64' and a second bore 66, 66' therethrough, each of the first 64, 64' and second 66, 66' bores having a center point 72, 72'

arranged to be offset from the center point 50 of the plate opening 36 of the tray trial 12 when the first guide 16, 16' is secured to the tray trial 12. (See, e.g., Appellants' specification at page 9, lines 3-5; page 12, lines 3-22; page 20, lines 3-13; page 24, lines 4-20; page 25, lines 4-9; and Figs. 7-9, 19-21, and 24-25.)

## **(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

Claims 1-18 and 21-28 stand rejected under 35 U.S.C. § 103 as being unpatentable over Wildgoose et al. (U.S. Patent No. 5,690,636) in view of Knox (U.S. Patent No. 6,332,887).

## **(7) ARGUMENT**

### **Rejection under 35 U.S.C. § 103 (Wildgoose/Knox)**

**Claims 1-18 and 21-28 Are Not Unpatentable over Wildgoose et al. (U.S. Patent No. 5,690,636) in view of Knox (U.S. Patent No. 6,332,887).**

### Discussion Regarding Patentability of Claim 21

#### *Claim 21*

Claim 21 reads as follows:

21. A method of surgically preparing a tibia for implantation of a prosthetic implant, comprising the steps of:  
    securing a tray trial to a proximal end of the tibia, wherein the tray trial defines a plate opening therethrough, the plate opening having a center point;  
    advancing a first bone working tool through the plate opening to form a first hole in the tibia;  
    securing a tool guide to the tray trial, wherein the tool guide defines a first bore and a second bore, each of the first and second bores having a center point offset from the center point of the plate opening;  
    determining a direction of offset of a medullary canal of the tibia from a center of the tibia; and  
    advancing a second bone working tool through one of the first bore and the second bore that corresponds to the direction of offset of the medullary canal to form a second bore in the tibia.

The invention defined in claim 21 addresses a particular problem in the medical arts. Specifically, a condition which renders surgical preparation relatively difficult is the case in which the tibial canal of the patient's tibia is offset



from, or otherwise not coincident with, the center of the tibia. Indeed, it is known that the anatomy of some patients may create a situation in which the tibial canal of the patient's tibia is offset from the center of the tibia by as much as three to four millimeters (3-4 mm). Such an offset is above and beyond a slight anterior-posterior offset of the tibial canal which is inherent in most patients' anatomies. It should be appreciated that if a tibial implant having a stem which is centered relative to the implant's plate is implanted into a patient's tibia which has an offset tibial canal, undesirable impingement of the stem into contact with the cortical bone of the tibia may result.

Applicants' invention of claim 21 is directed at overcoming, and in fact does overcome, the above-identified problem in the prior art. The Wildgoose reference never acknowledges this problem, much less, attempts to solve it. And the Knox reference, being directed at spinal fusion, is entirely unconcerned with this problem.

#### *Examiner's Proposed Combination of Wildgoose and Knox*

Presumably, the Examiner's proposed combination of Wildgoose and Knox set forth in the Final Office Action dated November 24, 2004 is to modify Wildgoose's punch guide 51 (see Fig. 1) so that its plate opening 55 possesses a shape similar to the configuration of the guide hole 328 of Knox' bushing 320 which is in the shape of two overlapping round holes, and thereafter utilize this modified punch guide and the rest of Wildgoose's system to create overlapping cuts in a tibia plateau of a patient, and thereafter implant a tibia prosthesis in the

cavity created by the overlapping cuts by using the implantation method otherwise taught by Wildgoose.

*Proposed Combination of Wildgoose and Knox Does Not Arrive at Invention of Claim 21*

The proposed combination of Wildgoose and Knox set forth in the Final Office Action dated November 24, 2004 does not arrive at the invention of claim 21. Recall that claim 21 recites the following limitations:

determining a direction of offset of a medullary canal of the tibia from a center of the tibia; and  
advancing a second bone working tool through one of the first bore and the second bore that corresponds to the direction of offset of the medullary canal to form a second bore in the tibia.

Neither Wildgoose nor Knox teaches these claimed steps. Again, Wildgoose does not acknowledge the problem of medullary canal offset, and thus Wildgoose contains no teaching regarding determining a direction of medullary canal offset. And further without the offset direction having been determined, Wildgoose does not further teach advancing a bone working tool through one of the two bores that *corresponds* with the determined offset direction. And the Knox reference, being directed at spinal fusion, is entirely unconcerned with the problem of medullary canal offset, and therefore Knox does not contain a teaching of either of the above-identified claimed steps.

Since neither Wildgoose nor Knox teach either of the two above-identified claimed steps, the combination of Wildgoose and Knox does not arrive at the invention of claim 21. Since the proposed combination of Wildgoose and Knox does not arrive at the invention of claim 21, a prima facie case of obviousness

under 35 U.S.C. § 103 has not been established with respect to the invention defined by claim 21.

*There Exists No Legitimate Teaching, Suggestion, or Incentive that Supports the Proposed Combination of Wildgoose and Knox*

Even if the proposed combination of Wildgoose and Knox was misconstrued to arrive at Appellants' invention of claim 21, one skilled in the art would not be motivated to combine Wildgoose and Knox as proposed. Indeed, in an attempt to identify a teaching, suggestion, or incentive that would support the above-identified proposed combination of Wildgoose and Knox, the following was stated in the 11/24/04 Final Office Action (see page 3, last two lines):

to create overlapping cuts in the selected tibia plateau.

However, one skilled in the art would not desire *to create overlapping cuts in the selected tibia plateau* since this would result in undesirable impingement of the prosthesis stem into contact with the cortical bone of the tibia. Drilling within the tibia in the proposed manner would create a space configured as two partially overlapping cylinders, one being on the lateral side of the approximate center point of the tibia, and the other being on the medial side. And in the case of a patient's tibial canal being offset from the approximate center of the tibia, one of these two overlapping cylindrical spaces would be created by drilling into a significant amount of cortical bone. Avoiding the creation of a stem space in cortical bone, and thus impingement of the stem into contact with the cortical

bone of the tibia, is exactly the problem that Appellants' invention of claim 21 is directed at overcoming.

Thus, modifying Wildgoose's punch guide 51 (see Fig. 1) so that its plate opening 55 possesses a shape of two overlapping round holes, and using such guide to create overlapping cuts in the tibia plateau would not have been obvious to one skilled in the art because this use of such a particularly configured guide would not be desirable in the surgical preparation of a tibia for implantation of a tibial implant. Indeed, using the combined Wildgoose/Knox tibial system having such a particularly configured guide in a manner consistent with the teachings of Wildgoose and Knox would arrive at an undesirable surgical result (i.e. cortical bone impingement), the type which Appellants' invention is directed at overcoming.

As a result, a legitimate teaching, suggestion, or incentive has not been identified that would support combining Wildgoose and Knox in the manner proposed, nor does one appear to exist. Thus, a prima facie case of obviousness under 35 U.S.C. § 103 has further not been established with respect to the invention defined in claim 21.

#### Discussion Re: Patentability of Claims 22-26

Each of claims 22-26 depends directly or indirectly from claim 21. As a result, each of claims 22-26 is allowable for, at least, the reasons hereinbefore discussed with regard to claim 21.

#### Discussion Re: Patentability of Claim 27

Claim 27 depends directly from claim 21. As a result, claim 27 is allowable for, at least, the reasons hereinbefore discussed with regard to claim 21.

Moreover, claim 27 recites:

further comprising the step of detaching the tool guide from the tray trial without any bone drill having been previously advanced through the other of the first bore and the second bore while the tool guide was secured to the tray trial.

The proposed combination of Wildgoose and Knox set forth in the Final Office Action dated November 24, 2004 further does not arrive at the invention of claim 27. Significantly, such proposed combination results in a method in which "overlapping cuts are made in the selected tibial plateau." If overlapping cuts are made as proposed, then both the first bore and the second bore of the tool guide would have been traversed by a bone drill while the tool guide was secured to the tray trial in contrast to limitations recited in claim 27. Thus, the proposed combination of Wildgoose and Knox set forth in the Final Office Action dated November 24, 2004 further does not arrive at the invention of claim 27. Consequently, a prima facie case of obviousness under 35 U.S.C. § 103 has further not been established with respect to the invention defined in claim 27.

#### Discussion Re: Patentability of Claim 28

Claim 28 depends directly from claim 27. As a result, claim 28 is allowable for, at least, the reasons hereinbefore discussed with regard to claim 27.

Moreover, claim 28 recites:

further comprising the step of detaching the tray trial from the proximal end of the tibia without any bone drill having been previously advanced through the other of the first bore and the second bore while the tray trial was secured to the proximal end of the tibia.

Similarly, if overlapping cuts are made as proposed, then both the first bore and the second bore of the tool guide would have been traversed by a bone drill while the tray trial was secured to the proximal end of the tibia in contrast to limitations recited in claim 28. Thus, the proposed combination of Wildgoose and Knox set forth in the Final Office Action dated November 24, 2004 further does not arrive at the invention of claim 28. As a result, a prima facie case of obviousness under 35 U.S.C. § 103 has further not been established with respect to the invention defined in claim 28.

#### Discussion Regarding Patentability of Claim 11

##### *Claim 11*

Claim 11 reads as follows:

11. A method of surgically preparing a tibia for implantation of a prosthetic implant, comprising the steps of:  
    securing a tray trial to a proximal end of the tibia, wherein the tray trial defines a plate opening therethrough, the plate opening having a center point;  
    advancing a first bone working tool through the plate opening at the center point to form a first hole in the tibia;  
    securing a first guide to the tray trial, wherein the first guide defines a first bore and a second bore, each of the first and second bores having a center point offset from the center point of the plate opening; and  
    advancing a second bone working tool through one of the first bore and the second bore to form a second bore in the tibia.

Similar to the above discussion regarding claim 21, one skilled in the art would not be motivated to combine Wildgoose and Knox in a manner that arrives

at Appellants' claim 11 as proposed. As stated above, the Examiner cited the following as motivation that purportedly supports the proposed combination:

to create overlapping cuts in the selected tibia plateau.

As discussed above, modifying Wildgoose's punch guide 51 (see Fig. 1) so that its plate opening 55 possesses a shape of two overlapping round holes, and using such guide to create overlapping cuts in the tibia plateau would not have been obvious to one skilled in the art because one skilled in the art would not desire *to create overlapping cuts in the selected tibia plateau*. Indeed, cutting overlapping cavities in a patient's tibial plateau would result in undesirable impingement of a prosthesis stem into contact with cortical bone of the patient's tibia. In short, an orthopedic surgeon would not want to make the proposed overlapping cuts on a patient's tibial plateau, and would not concoct such a system like the proposed Wildgoose/Knox system to do so. As a result, a legitimate teaching, suggestion, or incentive has not been identified that would support combining Wildgoose and Knox in the proposed manner, nor does one appear to exist. Thus, a prima facie case of obviousness under 35 U.S.C. § 103 has further not been established with respect to the invention defined in Appellants' claim 11.

#### Discussion Re: Patentability of Claims 12-18

Each of claims 12-18 depends directly or indirectly from claim 11. As a result, each of claims 12-18 is allowable for, at least, the reasons hereinbefore discussed with regard to claim 11.

#### Discussion Re: Patentability of Claim 1

The discussion regarding the patentability of claim 11 is relevant to the patentability of claim 1. As a result, claim 1 is allowable over the cited art.

#### Discussion Re: Patentability of Claims 2-10

Each of claims 2-10 depends directly or indirectly from claim 1. As a result, each of claims 2-10 is allowable for, at least, the reasons hereinbefore discussed with regard to claim 1.

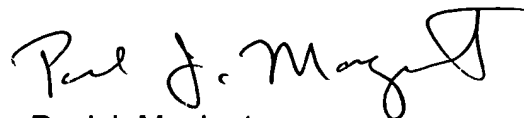


**(8) CONCLUSION**

Claims 1-18 and 21-28 are not unpatentable under 35 U.S.C. § 103 as being obvious over Wildgoose et al. (U.S. Patent No. 5,690,636) in view of Knox (U.S. Patent No. 6,332,887), and the Board of Appeals is respectfully requested to reverse the rejection of claims 1-18 and 21-28.

Respectfully submitted,

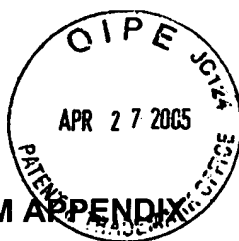
MAGINOT, MOORE & BECK

A handwritten signature in black ink, appearing to read "Paul J. Maginot", with a stylized flourish at the end.

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April 25, 2005

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**(9) CLAIM APPENDIX**

1. A surgical assembly for preparing a tibia for implantation of a prosthetic implant, comprising:

a tray trial adapted to be secured to a proximal end of the tibia and defining a plate opening therethrough, said plate opening having a center point; and

a first guide adapted to be secured to said tray trial, wherein said first guide defines at least a first bore and a second bore therethrough, each of said first and second bores having a center point arranged to be offset from said center point of said plate opening of said tray trial when said first guide is secured to said tray trial.

2. The surgical assembly of claim 1, wherein each of said first and second bores is configured to guide a bone working tool for advancement through said first guide and said plate opening of said tray trial.

3. The surgical assembly of claim 1, wherein said first and second bores overlap in said first guide.

4. The surgical assembly of claim 3, wherein said first guide defines a guide opening including said first and second bores and further including at least one blade receiving portion extending from at least one of said first and second

bores, said at least one portion configured to receive a cutting blade of a punch when the punch is advanced through said guide opening.

5. The surgical assembly of claim 4, wherein said guide opening of said first guide defines a first blade receiving portion extending from said first bore, a second blade receiving portion extending from said second bore and a third blade receiving portion extending from both said first and second bores.

6. The surgical assembly of claim 3, wherein:

said first guide defines a guide opening including said first and second bores, and includes a protrusion which extends into said guide opening at a location between said first and second bores to prevent movement of said bone working tool between said first and second bores without removal of the tool from said guide opening.

7. The surgical assembly of claim 1, further comprising a second guide which is adapted to be secured to said tray trial, wherein:

said second guide has an elongated bore extending therethrough,

said elongated bore has a center point, and

said center point of said elongated bore is aligned with said center point of said plate opening of said tray trial when said second guide is secured to said tray trial.

8. The surgical assembly of claim 7, further comprising a bone drill as the bone working tool, wherein:

said bone drill is advanced through said elongated bore of said second guide so as to drill a first hole in the tibia when said second guide is secured to said tray trial, and

said bone drill is advanced through one of said first and second bores in said first guide so as to drill a second hole in the tibia when said first guide is secured to said tray trial.

9. The surgical assembly of claim 8, wherein said first and second bores in said first guide are arranged relative to said center point of said plate opening in said tray trial so that said second hole drilled in the tibia overlaps said first hole drilled in the tibia.

10. The surgical assembly of claim 1, further comprising a drill bushing positionable in either of said first and second bores, said drill bushing defining a bushing bore therethrough configured to guide a bone working tool for advancement through said first guide and said plate opening of said tray trial.

11. A method of surgically preparing a tibia for implantation of a prosthetic implant, comprising the steps of:

securing a tray trial to a proximal end of the tibia, wherein the tray trial defines a plate opening therethrough, the plate opening having a center point;

advancing a first bone working tool through the plate opening at the center point to form a first hole in the tibia;

securing a first guide to the tray trial, wherein the first guide defines a first bore and a second bore, each of the first and second bores having a center point offset from the center point of the plate opening; and

advancing a second bone working tool through one of the first bore and the second bore to form a second bore in the tibia.

12. The method of claim 11, wherein:

the first guide defines a guide opening including said first and second bores; and

said method further comprises the step of advancing a punch through the guide opening of the first guide so as to form a punched hole in the tibia, wherein the punch advancing step is performed subsequent to the step of advancing a first bone working tool through one of the first and second bores.

13. The method of claim 11, wherein the first bone working tool is a bone drill.

14. The method of claim 11, wherein the second bone working tool is a bone drill.

15. The method of claim 14, wherein the first bone working tool is the same bone drill as the second bone working tool.

16. The method of claim 11, wherein the second bone working tool is a bone broach.

17. The method of claim 11, further comprising the step of advancing a third bone working tool, different from the second bone working tool, through the one of the first bore and the second bore subsequent to the step of advancing a first bone working tool through one of the first and second bores.

18. The method of claim 17, wherein the second bone working tool is a bone drill and the third bone working tool is a bone broach.

21. A method of surgically preparing a tibia for implantation of a prosthetic implant, comprising the steps of:

securing a tray trial to a proximal end of the tibia, wherein the tray trial defines a plate opening therethrough, the plate opening having a center point;

advancing a first bone working tool through the plate opening to form a first hole in the tibia;

securing a tool guide to the tray trial, wherein the tool guide defines a first bore and a second bore, each of the first and second bores having a center point offset from the center point of the plate opening;

determining a direction of offset of a medullary canal of the tibia from a center of the tibia; and

advancing a second bone working tool through one of the first bore and the second bore that corresponds to the direction of offset of the medullary canal to form a second bore in the tibia.

22. The method of claim 21, wherein:

the tool guide defines a guide opening that includes said first and second bores; and

the method further comprising the step of advancing a punch through the guide opening of the tool guide so as to form a punched hole in the tibia, wherein the punch advancing step is performed subsequent to the first bone tool advancing step.



23. The method of claim 21, wherein the first bone working tool is a bone drill.

24. The method of claim 23, wherein the second bone working tool is a bone drill.

25. The method of claim 24, wherein the first bone working tool is the same bone drill as the second bone working tool.

26. The method of claim 23, wherein the second bone working tool is a bone broach.

27. The method of claim 21, further comprising the step of detaching the tool guide from the tray trial without any bone drill having been previously advanced through the other of the first bore and the second bore while the tool guide was secured to the tray trial.

28. The method of claim 27, further comprising the step of detaching the tray trial from the proximal end of the tibia without any bone drill having been previously advanced through the other of the first bore and the second bore while the tray trial was secured to the proximal end of the tibia.